National Patient Safety Alert

MHRA

NovoRapid PumpCart in the Roche Accu-Chek Insight insulin pump: risk of insulin leakage causing hyperglycaemia and diabetic ketoacidosis

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This alert is for action by: All Healthcare institutions providing specialist diabetes services to patients

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by the clinical lead for diabetes and heads of procurement.

Explanation of identified safety issue:

The MHRA continues to receive serious reports of harm associated with insulin leakage for the NovoRapid PumpCart prefilled insulin cartridge in the Accu-Chek Insight Insulin pump. In some patients, there were serious consequences arising from inadequate supply of insulin, including diabetic ketoacidosis (DKA).

Although the manufacturer Roche Diabetes Care (RDC) has implemented a number of risk minimisation strategies to reduce the incidence of these events, the impact of these is inconclusive and we are taking further action to protect patients.

The main reasons for the leakages were:

1. The adapter needle being inserted in the insulin cartridge at an incorrect angle, which may cause bending of the needle and subsequent insulin leakage from the septum, in approximately 70% of cases;
2. Cracked cartridges, including non-visible hairline cracks, that may result from mechanical shocks such as dropping the cartridge or pump; in approximately 30% of cases;

Risk minimisation strategies have included technical improvements to the pump and adapter and safety communications on how to handle the pump and prefilled cartridge. An enhanced design of adaptor and tubing was implemented in September 2021 but events of leakage continue to be reported, albeit at reduced rates.

The manufacturer has released a Field Safety Notice (FSN) on this issue, which should be followed in addition to this alert. Patients should be informed of the importance of following the advice in the manufacturer's latest FSN. This includes using the new versions of adapter and tubing for certain lot numbers.

To protect patient safety, diabetes healthcare professionals should inform patients who use the Accu-Chek Insight of the risk of leakage. Clinical care decisions should be made to ensure patients are moved onto alternative pumps where possible.

Actions required

1. Identify whether you have any Roche Accu-Chek Insight Insulin pump devices in your organisation, or if you have provided them to patients under your care. Any affected stock should be quarantined.
2. Contact users of affected devices and undertake a patient-centred risk assessment (see additional information) to determine suitability to move onto an alternative pump based on individual risk.
3. Identify suitable alternative pumps and use local procurement procedures to acquire them.
4. Onboard patients to new pumps and ensure an appropriate follow-up period as per standard practice and guidance for initiating pump therapy within your organisation.
5. Patients with diabetes can continue to use affected devices if there is a lack of suitable alternative insulin therapy or if this has been deemed necessary after the patient-centred consultation. Any continued use of the affected device at any stage of the implementation of this alert requires a local risk assessment to be completed and documented (see additional information).

Actions should be fully completed in 6 months – by 26 November 2022

Additional information:

Information on adverse incidents

Cases with serious clinical consequences describing leakages of insulin, including cracked cartridges, in association with Accu-Chek Insight Pump and NovoRapid PumpCart Cartridges have been reported. In both 2020 and 2021, 25 serious cases each year (including cases where a patient required urgent medical treatment or hospitalisation) were reported to the MHRA in association with an insulin leakage event in UK patients, including 18 cases and 17 cases respectively of DKA.

So far in 2022 one case of DKA and 2 additional serious cases of hyperglycaemia have been reported to the MHRA in association with leakage events. In addition, non-serious cases of hyperglycaemia resulting from inadequate insulin supply have been also reported. In most cases, users did not require urgent medical intervention.

Risk assessment

A risk assessment must be recorded with all users. This should involve a discussion of the risks of continuing treatment with the affected device and consider the best interest of the patient and the management of their diabetes.

Patients presenting with unexplained hyperglycaemia identified as due to 'set failure' is a known risk experienced by users of insulin pumps. The issue associated with the Accu-Chek Insight pumps is different and is due to leakages directly from the reservoir, either by insulin escaping through cracks in the glass cartridge wall, or the cartridge septum not providing an adequate seal at the point of connection to the cannula. The leaked insulin can pool within the pump itself. As such, the problem may not be identified as quickly as other leaks since the user may not be aware of the leakage. If unidentified, the interrupted insulin delivery may lead to life-threatening consequences.

Effective training in the use of insulin pumps and continued vigilance of a patient's clinical presentation, combined with regular blood glucose monitoring, will reduce the likelihood of events such as hyperglycaemia and DKA. There is a risk that continued use of the Accu-Chek Insight pump with the prefilled glass cartridge may lead to leakages, particularly if the instructions for use are not followed closely

The use of multiple daily injections (MDI) insulin regimens or other non-pump insulin delivery devices while patients await the onboarding of a new insulin pump should only be considered if suitable training and support is provided and where the benefits outweigh the risks associated with discontinuation of the Accu-Chek Insight pump.

If the risk assessment indicates the patient's condition is best managed by continuing therapy with the Accu-Chek Insight pump, instruct patients not to use cartridges that have been dropped, even if there are no visible cracks. Cracks may develop over time following a drop or other mechanical shock. Inform users of the importance of following the advice in the manufacturer's latest FSN. This includes using the new adapter and tubing and checking the pump and cartridge regularly.

All versions of the Accu-Chek Insight pumps are affected by this action. To note, RDC ceased marketing the devices in the UK at the end of 2021 and new patients will not be offered the pump. Existing patients remaining on the Accu-Chek Insight pump will be fully supported until the end of their warranty only. The risk assessment should include a plan to move to an alternative therapy delivery device before the end of the warranty period.

Link to useful resources

NICE guidelines on issuing pumps

Stakeholder engagement:

This action has been endorsed by the Commission on Human Medicines (CHM) and its Expert Advisory Groups and the Device Expert Advisory Committee (DEAC).

MHRA have consulted with NHS England and NHS Improvement, and representatives from the Scottish, Welsh, and Northern Ireland Governments. MHRA have also conducted patient engagement activities with users of insulin pumps.

Please check website for when actions should be ceased or advice to check for date restriction are lifted.

Department of Health www.health-ni.gov.uk

NHS National Services Scotland

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